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Original Article

Safety and efficacy of Ahmed glaucoma valve implantation in refractory glaucomas in Northern Indian eyes

Suneeta Dubey [a,*], Vijeta Sharma [a,1], Anugya Agrawal [a], Lokesh Chauhan [a], Gordon Douglas [b]

Abstract

Purpose: To evaluate the safety and efficacy of Ahmed glaucoma valve (AGV) implantation in refractory glaucoma in Northern Indian eyes.
Background: The success rate of trabeculectomy remains low in cases of refractory glaucoma even with the use of antifibrotics. Glaucoma drainage devices have proven to be more efficacious in reducing intraocular pressure (IOP) in these glaucomas.
Methods: Retrospective records of 55 consecutive patients who underwent AGV implantation at Dr. Shroff's Charity Eye Hospital, New Delhi, India from January 2003 to December 2012 were reviewed. Pre-operative data included age, gender, eye laterality, specific diagnosis, number of anti-glaucoma medications, number of prior incisional surgeries, visual acuity and IOP on medical treatment. Postoperative data included visual acuity and IOP on day one, 1 week, 1 month, 3 months, 6 months, 1 year and yearly thereafter, number of anti-glaucoma medications, any complication or additional surgical intervention required. Success was defined as IOP >5 and <22 mmHg with or without treatment.
Results: Mean IOP decreased from 39.71 ± 8.99 pre-operatively to 17.52 ± 5.72 mmHg at last follow-up ($p < 0.001$) and number of medications reduced from 3.27 ± 0.84 to 1.25 ± 0.88 ($p < 0.001$). Visual acuity remained within one Snellen line or improved at last follow-up in 47 cases (85.4%). The cumulative probability of success was 85.45% at 1 year and 79.63% at 3 years. The incidence of post-operative complications was 25.45%.
Conclusion: AGV implantation has proven to be safe and is effective in controlling IOP in refractory glaucoma in Northern Indian eyes.

Keywords: Refractory glaucoma, Ahmed glaucoma valve, Intraocular pressure

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Introduction

Glaucoma is one of the leading causes of blindness worldwide.[1] Refractory glaucoma is the term used to define any kind of glaucoma that does not respond to medical or conventional surgical treatment.[1–4] The most commonly performed surgical procedure for glaucoma is trabeculectomy with or without anti-fibrotic agents.[5–10] Various modifications have been tried to improve the success of trabeculectomy such as use of anti-fibrotic agents and mechanical barriers, but still the success rate remains low in cases of refractory glaucoma. Glaucoma drainage devices (GDDs) have proven to be more efficacious in reducing intraocular pressure (IOP) in refractory glaucomas.[11,12]

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[a] Dr. Shroff's Charity Eye Hospital, 5027, Kedarnath Road, Daryaganj, New Delhi 110002, India
[b] University of Calgary, 2500 University Dr NW, Calgary, AB T2N 1N4, Canada

* Corresponding author. Address: 814, Technology Apartment, IP Extension, Patparganj, Delhi 110092, India. Tel.: +91 9818224290.
e-mail addresses: dubeysuneeta@hotmail.com (S. Dubey), vijeta01.dhiman@gmail.com (V. Sharma), anugya.agrawal83@gmail.com (A. Agrawal), lokesh@sceh.net (L. Chauhan), seaview10@shaw.ca (G. Douglas).
URL: http://www.sceh.net (S. Dubey).
[1] Tel.: +91 7838878710.

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In 1969, Molteno introduced the first drainage implant with a long silicone tube attached to a thin acrylic plate.[13,14] All currently available GDDs are based on the concept of the Molteno implant with various modifications such as introduction of a valve mechanism or variations in surface area of the end plate.

The Ahmed glaucoma valve® (AGV) (New World Medical Inc., Rancho Cucamonga, CA, USA) is a shunt device with a built-in Venturi valve which opens at a specific level of IOP, thus reducing the chances of hypotony in the early post-operative period.[15] The valve may act as a potential site for obstruction by inflammatory debris, especially in Asian eyes that are known to have more severe reactions.[16] The purpose of the present study is to evaluate the safety and efficacy of AGV implants in refractory glaucomas in a Northern Indian population.

Materials and methods

This is a retrospective cohort study of 55 patients with refractory glaucoma, who underwent AGV implantation at Dr. Shroff's Charity Eye Hospital, New Delhi, India from January 2003 to December 2012.

Patients of all ages and both genders with refractory glaucoma unresponsive to conventional medical and surgical therapy or significant conjunctival scarring or inflammation precluding trabeculectomy were included. Patients were excluded if they had irregular or inadequate (<3 months) follow up. Two patients were excluded because of irregular follow-up from a pool of 57 patients. The Institutional review board approval was obtained for this research. Further, written informed consent also was obtained from each participant.

Data collection

Pre-operative data were collected from patients' records including age at the time of surgery, gender, eye laterality, specific glaucoma diagnosis, number of anti-glaucoma medications used pre-operatively, number of prior incisional surgeries, visual acuity and pre-operative IOP on medical treatment. Postoperative data included visual acuity and IOP on day one, 1 month, 3 months, 6 months, 1 year and yearly thereafter, number of anti-glaucoma medications used post-operatively, any significant intra-operative or post-operative complications and any additional surgical intervention if required.

Surgical technique

The surgical procedure consisted of AGV implantation (models S2, S3, FP7, FP8) using a standardized surgical technique by a single experienced surgeon (SD). Surgery was done after obtaining informed written consent under peribulbar or general anesthesia. After applying a superior rectus bridle suture or corneal traction suture, a fornix-based conjunctival flap and tenon's capsule were dissected to allow insertion of the plate of the implant into sub-tenon's space 8 mm behind the corneal limbus. Before insertion of the plate, the valve of the implant was primed with balanced salt solution (BSS®, Alcon, Fort Worth, TX, USA). The plate was fixed to the sclera with 9–0 black nylon sutures (Ethicon®, Alcon, Fort Worth, TX, USA). The tube was shortened to the desired length with its sharp bevel facing anteriorly to allow 2–3 mm of tube in anterior chamber. An anterior chamber (AC) paracentesis wound was created at the peripheral cornea and sodium hyaluronate 1% (Healon®, Abbott Medical Optics) was injected to prevent collapse of the AC after sclerostomy was made. To prevent tube movement, a radial groove was made in the sclera at the proposed site & the edges of the groove were retracted using mild cautery. The tube of the implant entered the AC parallel to the iris plane through the sclerostomy made with a 23 gauge syringe needle. For ease of entry, the needle was bent in a Z-shaped manner. In pseudophakic patients with post-penetrating keratoplasty (post-PK) glaucoma and peripheral anterior synechiae, the tube was placed in the ciliary sulcus. Concurrent anterior or pars plana vitrectomy was performed in aphakic patients and in patients in whom pars plana insertion of tube was planned. The tube was fixed to the sclera with 9–0 black nylon (Ethicon, Ethilon) suture. The anterior part of the tube was covered with a donor scleral patch graft, which was then fixed to the sclera with 9–0 black nylon sutures. The conjunctiva was closed with 8–0 polyglactin suture (Vicryl®; Ethicon, Inc., Somerville, NJ, USA). The sodium hyaluronate in the AC was removed as much as possible through the paracentesis site. No adjunctive antimetabolite was used in any of the cases. Patients with neovascular glaucoma were treated with panretinal photocoagulation and/or intravitreal bevacizumab (Avastin®, Genentech, South San Francisco, CA, USA) before the AGV was implanted.

Postoperatively, all patients received intensive steroid, antibiotic and cycloplegic drops daily. The antibiotic drops were stopped at 2 weeks postoperatively, and steroid drops were tapered gradually over 4–8 weeks.

All the parameters studied for the postoperative evaluation were documented on each follow-up wherever possible and decisions to start antiglaucoma medications or to perform other surgeries were taken accordingly.

Success criteria

Success was defined as IOP >5 and <22 mmHg with or without anti-glaucoma treatment. Failure was defined as IOP <5 or >22 mmHg using every available glaucoma medication that the patient could topically or systemically tolerate[17] (maximal medical therapy or MMT), need for additional glaucoma surgery or loss of light perception. Results of the most recent examination were used to record the final IOP for classification as a success or failure. Preoperative IOP was recorded on the most recent visit prior to surgery. IOP was measured with a Goldmann applanation tonometer, a handheld applanation tonometer (Kowa®, Kowa Optimet Inc., Torrance, CA, or Perkins®, Clement Clarke, Columbus, OH) or a Tono-pen® (Mentor O & O, Norwell, MA).

Statistics

Statistical analysis was done using the SPSS software® (Chicago, Illinois). The Kolmogorov–Smirnov test was used to test for normality of numeric variables. For comparisons of two normally distributed numerical variables, we used paired Student's *t* tests to determine any significant changes